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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,902	01/11/2001	Roberts S. David	PC9047D	1327

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EXAMINER

SHAHNAN-SHAH, KHATOL S

ART UNIT PAPER NUMBER

1645

DATE MAILED: 12/14/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,902

Applicant(s)

DAVID ET AL.

Examiner

Khatol S Shahnan-Shah

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1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Applicants' preliminary amendment, received 1/11/2001, paper # 2 is acknowledged.

Claims 1-17 were canceled, new claims 18-19 were added. Specification page 1, priority statement was inserted.

2. Currently claims 18-19 are pending and under consideration.

Information Disclosure Statement

3. Information Disclosure Statement paper # 3 received 1/11/2001 is acknowledged.

Applicants directed examiner's attention to references that were made of record in grandparent and parent applications serial No. 08/536,970 and 09/413,524. The examiner did not locate all copies of those references from those applications. Examiner respectfully requests the applicants to provide copies of the missing references.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derived" in claim 18 is a relative term, which renders the claim indefinite. It is unclear what constitutes the metes and bounds of that encompassed by "an antigen derived from a respiratory virus".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (The veterinary record, May 2, 1987) and Geresi et al. (Ann. Immuno. Hung Vol. 25, pp. 37-40 1985) in view of Wu et al. (The Journal of Immunology, Vol. 148, pp. 1519-1525, 1992) and Gluck et al. (US Patent 5,879,685).

Claims are drawn to a multicomponent clostridial vaccine composition comprising a viral antigen and a saponin adjuvant.

Green et al. teach the formulation of a multivalent clostridial vaccine in analogous art (see page 435) for the purpose of stimulating a protective immune response against multiple strains and species of this pathogen. Green et al. teach multicomponent clostridial vaccines such as Covexin 8, Hepatavac and Tasvax (see table 1). Green et al. teach the inclusion of six or more clostridial immunogens such as toxoids from *Cl. chauvoei*, *Cl. septicum*, *Cl. tetani*, *Cl. nvoyi*, *Cl. haemolyticum* and *Cl. perfringins* (type B, C and D) for the realized reduced threat of loss of livestock, wherein the use of six or more of clostridial immunogens would have provided for a broader range of immune response against clostridial pathogens and increase the likelihood of protection against infection by a broader range of species or strains of clostridium. Green et al.

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teach aluminum hydroxide as the adjuvant (page 438, column 1). Green et al. do not teach viral antigen.

Geresi et al. teach the formulation of multivalent clostridial vaccine compositions, which also comprise a viral immunogen (see page 38). The reference differs from the instantly claimed invention by failing to show the use of saponin as an adjuvant.

Wu et al. show the use of saponin adjuvant in association with an antigen, wherein the exemplified vaccine comprised a viral antigen (see abstract and results in page 1521 and discussion in page 1523). Wu et al. teach that vaccine formulations containing the saponin adjuvant produced significantly higher titers of antibody than alum absorbed vaccines. Wu et al. do not teach a respiratory virus.

Gluck et al. teach an immunostimulating combination of influenza virus and *Clostridium tetani* (see abstract and claims 6-9).

Therefore, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to modify or combine the compositions of Green et al. and Geresi et al., include a respiratory virus taught by Gluck et al. and to include the saponin adjuvant of Wu et al. because all of the references are directed to the formulation of vaccines for the attainment of enhance immune response. One with ordinary skill in art would have been motivated to combine these compositions because Green et al and Geresi et al. both teach the formulation of multicomponent clostridial vaccines, Gluck et al. and Geresi et al. teach the inclusion of viral antigens in bacterial vaccine composition and Wu et al. teach the use of saponin as an adjuvant which provides for an enhanced immune response when in association with either a clostridial antigen or a viral antigen, respectively. In the absence of unexpected

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results, Green et al. and Geresi et al., in view of Gluck et al. and Wu et al. obviate the instantly claimed invention.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah 2/11/01

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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Rodney P Swartz

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER